

VT SUPERIOR COURT
WASHINGTON UNIT
CIVIL DIVISION

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**STATE OF VERMONT
SUPERIOR COURT
WASHINGTON UNIT**

FILED

IN RE)
AMPHASTAR PHARMACEUTICALS, INC.)

CIVIL DIVISION
Docket No. 800-12-15 Wncw

ASSURANCE OF DISCONTINUANCE

Vermont Attorney General William H. Sorrell ("the Attorney General") and Amphastar Pharmaceuticals, Inc. ("Amphastar") hereby agree to this Assurance of Discontinuance ("AOD") pursuant to 9 V.S.A. § 2459.

REGULATORY FRAMEWORK

1. Vermont's Consumer Protection Act prohibits "[u]nfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce." 9 V.S.A. § 2453

BACKGROUND

2. Amphastar is a Delaware corporation with its principal offices and place of business located at 11570 6th Street, Rancho Cucamonga, California 91730. It is a specialty pharmaceuticals company that is engaged in the development, manufacture and marketing of proprietary and generic injectable and inhalation products, including the generic drug Naloxone.

3. Naloxone is an opioid antagonist. With proper, timely administration, it negates or neutralizes the effects of an overdose of heroin or another opioid. Naloxone is used in Vermont to reduce the rates of death due to overdose.

4. Vermont and other states are confronting a profound public health challenge, as the number of heroin and opioid-related deaths continues to increase.

5. The State of Vermont, local governments in Vermont, and associated public entities, including but not limited to the Vermont Department of Health and the governments of individual Vermont municipalities, counties and communities, likewise established programs to respond to the heroin and opioid epidemic by distributing, purchasing, or funding the purchase of Naloxone.

6. Amphastar raised prices for its current Naloxone products in or about the fall of 2014.

7. The Governor of Vermont transmitted a letter to Amphastar dated April 8, 2015 in which he expressed concern that the increase in the price of Naloxone could adversely affect access to the drug in Vermont.

8. While the Attorney General alleges that the increase in Naloxone prices constitutes an unfair and deceptive act and practice under 9 V.S.A. § 2453, Amphastar maintains that its pricing of Naloxone is based upon legitimate and lawful business factors.

9. In a mutual good faith effort to amicably resolve VTAG's stated pricing concerns, the parties have engaged in discussions regarding Amphastar's Naloxone pricing. Amphastar and VTAG each believe that the obligations imposed by this agreement are beneficial to the public and will improve access to Naloxone, and will potentially save lives.

TERMS OF AGREEMENT

10. Payment Amount

- a. Amphastar shall make a payment ("Payment") in the amount of \$6.00 (the "Payment Amount") for each Amphastar Naloxone Syringe (a "Syringe") purchased by a Public Entity in Vermont, or where the purchase price is

reimbursed by a Public Entity in Vermont. For purposes of this Agreement, a "Public Entity" is any non-federal governmental entity located in Vermont, including but not limited to state agencies, county or other local governments and their agencies, or law enforcement agencies. In the event that a Public Entity distributes or resells Syringes to other Public Entities, the Vermont Agency of Administration ("AOA"), on behalf of the State of Vermont, will only permit the last purchaser to receive reimbursement for a Syringe.

- b. Amphastar shall pay the Payment Amount associated with a given Syringe regardless of whether the Syringe was purchased directly from Amphastar or from a third party (including wholesale distributors). In no event shall the Payment Amount be reduced.

11. Payment Increase. Notwithstanding paragraph 10, in the event Amphastar increases its wholesale acquisition cost ("WAC") of a Naloxone Syringe ("WAC Increase"), Amphastar shall increase the Payment Amount by the actual dollar amount of the WAC Increase to offset any increase in the Syringe price. However, in no event shall the Payment Amount be reduced. During the Term (as defined in paragraph 15 below), Amphastar shall notify AOA within 30 days following any wholesale price increase of Naloxone to Public Entity Purchasers.

12. Payment Procedures. When seeking Payments under this Agreement, AOA shall request from the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP") (the group purchasing organization for state governments which negotiates the purchase price paid to Amphastar for Naloxone by state governments, including Vermont) and submit to Amphastar, the Vermont Naloxone Detailed Report of the number of Naloxone Syringes

purchased or reimbursed by a Public Entity during a given quarter, i.e., a three (3) month time period, within sixty (60) days of the conclusion of the quarter. Within sixty (60) business days of receipt of the Vermont Naloxone Detailed Report, Amphastar shall pay the total accrued Payment Amounts reflected in the Consolidated Request to AOA. AOA shall thereafter disburse the Payments to the Vermont Agencies as required, in a timely manner.

13. Term and Termination. This Agreement shall apply to Syringes purchased within one (1) year following the Effective Date of this Agreement (the "Term"). Following the payment of all Payment Amounts accrued during the Term and submitted for reimbursement pursuant to paragraph 3, this Agreement shall terminate ("Termination"), except for paragraphs 15 through 21, which shall survive Termination.

14. Liability Exclusion. Except as otherwise may be stated herein, Amphastar's liability under this Agreement is limited to payment of the Payment Amount for Syringes purchased during the Term, and Amphastar otherwise shall assume no further liability pursuant to this Agreement, including liability for damages of any type (including direct, indirect, and consequential damages). Except as provided in paragraph 16 below, however, nothing in this Agreement shall be construed to alter or limit Amphastar's existing legal obligations or liabilities, including but not limited to those arising from the manufacture or marketing of Naloxone.

OTHER TERMS

15. The Attorney General finds the financial relief and other obligations set forth in this agreement to be in the public interest, accepts the terms of this Agreement, pursuant to 9 V.S.A. § 2459, in lieu of the commencement of any legal proceeding, and agrees not to take legal action against Amphastar or any of its Affiliates, predecessors, successors, parents,

subsidiaries, assigns, agents, administrators, attorneys, directors, shareholders, officers, employees, or representatives in connection with its 2014 pricing of Naloxone.

16. Nothing in this Agreement shall be construed as an admission or concession by Amphastar of any liability in connection with Naloxone, including with respect to Amphastar's pricing, sales, manufacture, and marketing thereof.

17. Amphastar expressly disclaims any endorsement or promotion of off-label use by VTAG and/or any Vermont Agency of any of Amphastar's products, including Amphastar's Naloxone.

18. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

19. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

20. This Agreement shall be governed by and interpreted under the laws the State of Vermont without regard to its conflict or choice of law provisions. Amphastar agrees not to raise or interpose in any way their state of incorporation as a defense on grounds of personal jurisdiction as to any cause of action, claim, or argument arising from the enforcement of this Agreement by the Attorney General or any Vermont Agency.

21. The Parties agree that any Vermont Agency purchasing Naloxone during the Term constitutes an intended third-party beneficiary of this Agreement.

22. This Agreement constitutes the entire agreement by and between the Parties as to the subject matter hereof.

23. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

24. The Superior Court of the State of Vermont, Washington Unit, shall retain jurisdiction over this AOD and the parties for the purpose of enabling the Attorney General to apply to this Court at any time for orders and directions as may be necessary or appropriate to enforce compliance with or punish violations of this AOD.

25. By signing below, Amphastar voluntarily agrees with, and submits to, the terms of this AOD.

DATED at Rancho Cucamonga, California, this 14th day of December, 2015.

By: 

Jason Shandell

Title: President

Amphastar Pharmaceuticals, Inc.

ACCEPTED on behalf of the Attorney General

DATED at Montpelier, Vermont this 16th day of December, 2015.

STATE OF VERMONT

WILLIAM H. SORRELL
ATTORNEY GENERAL

By: 

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